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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,198	05/14/2001	Rudolf H. Aebersold	P-IS 4693	2506

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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

13

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/858,198

Applicant(s)

AEBERSOLD ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 1-75,87-89,91,100-102 and 104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 76-86,90,92-99,103 and 105 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 11.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1) Applicants' election without traverse of the invention of Group II, claims 76-105, as defined by the first structure of Figure 1 is acknowledged (Paper No. 10). Claims 1-75 and 87-89, 91, 100-102, and 104 are withdrawn from further consideration as being drawn to non-elected inventions. Claims 76-86, 90, 92-99, 103, and 105 have been examined on the merits to the extent that they encompass the elected invention as defined by the first structure of Figure 1.

2) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

3) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 76-86, 90, 92-99, 103, and 105 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation and use of the "solid support" coupled to a "chemical group" as defined by the first structure of Figure 1, does not reasonably provide enablement for a "composition" comprised of a "solid support" coupled to any and all possible "cleavable functional groups", "tags", and "reactive groups" (either uncoupled {claim 94} or coupled to a "sample molecule" {claim 76}). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Enablement is present in the specification for the production and use of the "composition" depicted in the first structure of Figure 1. The specification fails to provide an enabling written description, either generic or specific, and commensurate in scope with the claims, of how to prepare and use all "compositions" comprising any and all "cleavable functional groups", "tags" and "reactive groups" configured "relative to each other to allow transfer of said tag to said sample molecule upon cleavage of said cleavable functional group". Other than the structure of Figure 1, the specification fails to provide even a minimal generic description of the spatial configuration of the moieties which define the "chemical group", the actual chemical structures involved and how these structures are linked. The statement that the moieties which constitute the "chemical group" are "positioned relative to each other to allow..." does not provide an adequate description to enable a skilled artisan to assess the exact scope of the claim nor to be able to prepare "compositions" other than that of Figure 1. For example, the specification provides no guidance as to how one skilled in the art would prepare a "chemical group" which would meet the "relative to each other..." limitation wherein the "cleavable functional group" is cleavable by acid or base (page 15, lines 25-26), the "reactive group" is an azido moiety and the "tag" is an enzyme; yet this combination, and a wide variety of others which involve very different chemistries, are encompassed by the claims.

Enablement is further lacking for the preparation and use of a variety of configurations which are encompassed by the claim language. For example, there is no enabling support for the configuration in which the "tag" is directly attached to the "solid support" and both the "sample" and "cleavable functional group" are separately attached as pendant groups on the "tag". In this case, cleavage of the "cleavable functional group" would "allow transfer of said tag to said sample molecule" *as well as* allowing the "solid support" to remain attached to the "sample". This configuration is encompassed by the claim language.

6) Claims 76-86, 90, 92-99, 103, and 105 are rejected under 35 USC 112, second paragraph, as being indefinite and/or confusing for the following reasons.

a) It is unclear what is meant by the term "a second messenger" of claim 77.

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b) In claims 90 and 103, it is unclear what is meant by the term "a characteristic isotope distribution".

c) Claims 76-86, 90, 92-99, 103, and 105 are indefinite for the reason that it is unclear from the claim language where the "solid support" ends up after the "transfer of said tag to said sample" (see the third sub-paragraph under paragraph **5**) above).

7) Claims 76-86, 90, 92-99, 103, and 105 are rejected under judicial doctrine as being drawn to an improper Markush group. The claimed compositions are directed to conjugates comprised of multiple variables recited as a "solid support", a "cleavable functional group", a "tag" and a "reactive group". The claimed conjugates, each of which comprises a composite structure defined by this combination of variables, do not contain a core substantial structure, common to all members of the group, which is essential to the disclosed utility. In the absence of such a structural core common to all of the conjugates, the claims are drawn to improper Markush group.

8) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10) Claims 76-78, 82-84, 90, and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Gygi et al (Nature Biotechnology, Vol. 17, October 1999, pages 994-999).

Gygi et al describe a composition which anticipates the composition of instant claim 76: i.e. an avidin affinity chromatography column (a "solid support") "coupled" via a biotin linker to an ICAT linker (a "tag") which is coupled to a peptide/protein sample through a thiol-specific reactive group (a "reactive group covalently linked to a sample"). The protein/peptide of the reference includes a "cleavable functional group", i.e. the protein/peptide may be cleaved by a protease. Upon protease cleavage the "tag" is transferable to the "sample" as required by the instant claims. See Figures 1 and 2; first paragraph under "Results and discussion" of page 994.

11) Claims 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gygi et al (Nature Biotechnology, Vol. 17, October 1999, pages 994-999).

Gygi et al is applied for its description of the conjugates as set forth in the above rejection under 35 USC 102(b). The features of the dependent claims are either described by the reference (e.g. for the polypeptide modifications of claims 79 and 80 see the different "cell states" of Figure 2) or constitute obvious variations in parameters which are routinely modified in the art (e.g. the choice of a well known solid support of claim 81) and which have not been described as critical to the practice of the invention.

12) A claim drawn to the first structure of Figure 1 (encompassed by claim 94) in which the leucine moiety is designated as containing a detectable isotope (specification, page 23, lines 8-14) would be free of the prior art and would be allowable. Without the designation of a detectable isotope moiety, the compound would not contain a required "tag".

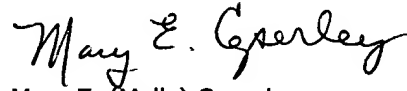
13) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

April 04, 2003


Mary E. (Molly) Ceperley
Primary Examiner
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